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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/993,739      | 11/23/2001  | Dosuk D. Lee         | 112430.134US7       | 1714             |

23483 7590 03/27/2003

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EXAMINER

LEVY, NEIL S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 03/27/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

973739

Applicant(s)

Lee et al

Examiner

Moxley

Group Art Unit

16/69

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/28/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 18-31 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 18-31 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6, 7
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Receipt is acknowledged of Declaration, Amendment, RCFR, IDS, Sup. IDS.

Please provide dates and for this files references for those lined out, please provide an abstract on a single page.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Word(s) seem to be missing, which?

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18~~31~~<sup>2</sup> is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al 582062 in view of niwa 4429691 and Sugihara et al WO 9000892.

Constantz provides self-hardwize CaP composition with adjustable setting time depending on intended use (col. 2, Summary, line 43-53). Particles are mixed (col. 4), with supplemental materials, and tetra calcium phosphate and fluid (water) is added (col. 5, lines 54-66). Supplementals include bone protein, collagen, matrix protein, the instant decriminalized bone matrix (col. 6, lines 25-35). The mix is injectable paste (col. 7, lines 33-44, 63 and sets.

The invention utilizes a mix of CaP (col. 3, lines 21-40), including amorphous forms and CaP at 1.67 ratio – hydroxyapatitic, with total CaP of 1.1-2:1, thus inclusive of the instant range. The constitutes instant claim 18. Variation is ratio of Ca:P permits control of resorption rate. The instant claim 21 CaP are disclosed here. The 1.1-2:1 Ca:P ratio is also within the 5:1 to 1:5 weight ratio of the instant claim 25. DCPD (Brushited is also disclosed. Additives are at 1-25%, the instant claim 28, 29 ranges, and are in particulate form (col. 6, last paragraph). Fluid is 15-70% of the total composition, the instant claim 27, and can be shown or buffered solution (claim 1). Absent grain size or Fiber form. However, Niwa shows the same bone replacement (col. 4, top) hydroxyapatitic components, and teaches grain size of the instant claims, to be important in order to promote new bone form action (col. 4, lines 14-36). Sugihara also show bone replacement apatitic composites, and includes Fiber form of supplemental material (p.5, bottom).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an effective, stable bone cement, to utilize Constantz, modified with added components to provide strength, delivery of drugs and/or bone replacement template. It has not clearly been established by objective showing of some unobvious and/or unexpected results that the particular forms of active, their ratios or additives provides any greater any greater level of prior art expectation as claimed. Further, applicant has showed no criticality as to the ingredient concentrations, ratios or Application.

The selection of each ingredient and form thereof is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredients to optimize the effects desired, and the use ingredients for the functionality for which they are known to be used is not a basis for patentability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Levy/LR  
March 24, 2003

NEIL S. LEVY  
PRIMARY EXAMINER